March 9, 2015

Spectrum Pharmaceuticals Announces FDA's Acceptance of NDA Filing for Captisol-Enabled™ (Propylene Glycol-Free) Melphalan

- PDUFA decision expected October 23, 2015, 10 months from NDA filing.
- Approval is being sought for use as a high-dose conditioning treatment prior to stem cell transplantation in multiple myeloma and for the palliative treatment of patients with multiple myeloma for whom oral therapy is not appropriate.
- Spectrum's formulation is propylene-glycol free and is more stable with a longer use time, which could simplify clinical administration logistics.
- The Company plans to launch this drug with its existing hematology/oncology sales force pending approval.

HENDERSON, Nev.--(BUSINESS WIRE)-- **Spectrum Pharmaceuticals (NasdaqGS: SPPI)**, a biotechnology company with fully integrated commercial and drug development operations with a primary focus in Hematology and Oncology, today announced that its New Drug Application (NDA) for Captisol-Enabled Melphalan (CE-Melphalan), has been accepted by the U.S. Food and Drug Administration (FDA). The FDA has assigned a Prescription Drug User Fee Act (PDUFA) action date of October 23, 2015 for the CE-Melphalan NDA, which is 10 months from the filing date. Spectrum is seeking FDA approval for its use as a high-dose conditioning treatment prior to autologous hematopoietic (progenitor) stem cell transplantation (AHCT) in patients with multiple myeloma (MM), an orphan drug designation. Spectrum is also seeking approval for the palliative treatment of patients with MM for whom oral therapy is not appropriate.

"We are excited the CE-Melphalan filing has been accepted by the FDA, representing another important company milestone," said Rajesh C. Shrotriya, MD, Chairman and Chief Executive Officer of Spectrum Pharmaceuticals. "CE-Melphalan met all pivotal trial endpoints, and we expect to launch this drug if approved, using our existing sales force towards the end of the year. The drug's improved solubility and stability should make it an attractive treatment option for both transplant conditioning and the palliative treatment of patients with MM. Eliminating the need for propylene glycol in the preparation of CE-Melphalan eliminates the risk of the toxicities associated with this excipient. In addition, CE-Melphalan's increased stability simplifies the logistics for pharmacies and nursing staff, and is anticipated to allow for longer infusion times which may permit the administration of higher dose intensities. We anticipate these characteristics of CE-Melphalan will facilitate rapid adoption. We look forward to bringing this drug to market and providing additional treatment options to patients suffering with cancer."

The Phase 2 pivotal trial evaluating CE-Melphalan was a multi-center trial evaluating safety and efficacy. The primary objective of the study was to determine the overall safety and toxicity profile in MM patients receiving 200 mg/m^2 of CE-Melphalan as myeloablative therapy prior to AHCT. The secondary objectives evaluated the efficacy of CE-Melphalan in this patient population as measured by Multiple Myeloma Response Rate (according to International Myeloma Working Group [IMWG] criteria), and the rates of myeloablation and engraftment. Study results support the safety and efficacy of high-dose CE-Melphalan as a high-dose conditioning treatment prior to AHCT in patients with MM. CE-Melphalan led to successful myeloablation and subsequent engraftment in all (100%) of the MM patients studied with no mortality or unexpected transplant-related toxicity. Overall, 95% of subjects (n=61) responded to high dose CE-Melphalan, and 67% VGPR or better responses were achieved in the subgroup of high risk patients (15%). There were no deaths by Day 100, and the most common Grade 3 and 4 toxicities were the expected hematologic events (neutropenia, leukopenia, lymphopenia, thrombocytopenia and anemia). The most frequent non-hematologic adverse events included diarrhea, nausea, and fatigue. Importantly, the incidence of severe mucositis was low (Grade 3/4; 10%).

Spectrum Pharmaceuticals gained global development and commercialization rights to CE-Melphalan from Ligand Pharmaceuticals Incorporated (NASDAQ: LGND) in March 2013. Spectrum assumed the responsibility for the pivotal clinical trial and was responsible for filing the NDA. Under the license agreement, Ligand received a license fee and is eligible to receive milestone payments, as well as royalties following potential commercialization.

About Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals is a leading biotechnology company focused on acquiring, developing, and commercializing drug products, with a primary focus in oncology and hematology. Spectrum and its affiliates market five oncology drugs— FUSILEV® (levoleucovorin) for Injection in the U.S.; FOLOTYN® (pralatrexate injection), also marketed in the U.S.; ZEVALIN® (ibritumomab tiuxetan) Injection for intravenous use, for which the Company has worldwide marketing rights; MARQIBO® (vinCRIStine sulfate

LIPOSOME injection) for intravenous infusion, for which the Company has worldwide marketing rights and BELEODAQ® (belinostat) for Injection in the U.S.. Spectrum's strong track record in in-licensing and acquiring differentiated drugs, and expertise in clinical development have generated a robust, diversified, and growing pipeline of product candidates in advanced-stage Phase 2 and Phase 3 studies. More information on Spectrum is available at www.sppirx.com.

About Captisol-Enabled Melphalan

Captisol-Enabled, Propylene Glycol -free Melphalan is a novel intravenous formulation of melphalan being investigated for the multiple myeloma transplant setting, for which it has been granted an Orphan Drug Designation by the FDA. This formulation eliminates the need to use propylene glycol containing custom diluent, which has been reported to cause renal and cardiac side effects, which in turn limit the ability to deliver higher doses of therapeutic compounds. The use of the Captisol® technology to reformulate melphalan also improves its stability and is anticipated to allow for slower infusion rates and longer administration durations, potentially enabling clinicians to safely achieve a higher dose intensity for pre-transplant chemotherapy.

About Captisol®

Captisol is a patent-protected, chemically modified cyclodextrin with a structure designed to optimize the solubility and stability of drugs. Captisol was invented and initially developed by scientists in the laboratories of Dr. Valentino Stella at the University of Kansas' Higuchi Biosciences Center for specific use in drug development and formulation. This unique technology has enabled six FDA-approved products, including Onyx Pharmaceuticals' Kyprolis®, Baxter International's Nexterone® and Merck's NOXAFIL IV. There are also more than 30 Captisol-enabled products currently in clinical development.

Forward-looking statement — This press release may contain forward-looking statements regarding future events and the future performance of Spectrum Pharmaceuticals that involve risks and uncertainties that could cause actual results to differ materially. These statements are based on management's current beliefs and expectations. These statements include, but are not limited to, statements that relate to our business and its future, including certain company milestones, Spectrum's ability to identify, acquire, develop and commercialize a broad and diverse pipeline of late-stage clinical and commercial products, leveraging the expertise of partners and employees around the world to assist us in the execution of our strategy, and any statements that relate to the intent, belief, plans or expectations of Spectrum or its management, or that are not a statement of historical fact. Risks that could cause actual results to differ include the possibility that our existing and new drug candidates may not prove safe or effective, the possibility that our existing and new applications to the FDA and other regulatory agencies may not receive approval in a timely manner or at all, the possibility that our existing and new drug candidates, if approved, may not be more effective, safer or more cost efficient than competing drugs, the possibility that our efforts to acquire or in-license and develop additional drug candidates may fail, our lack of sustained revenue history, our limited marketing experience, our dependence on third parties for clinical trials, manufacturing, distribution and quality control and other risks that are described in further detail in the Company's reports filed with the Securities and Exchange Commission. We do not plan to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this press release except as required by law.

Spectrum Pharmaceuticals
Shiv Kapoor, 702-835-6300
Vice President, Strategic Planning & Investor Relations
InvestorRelations@sppirx.com

Source: Spectrum Pharmaceuticals